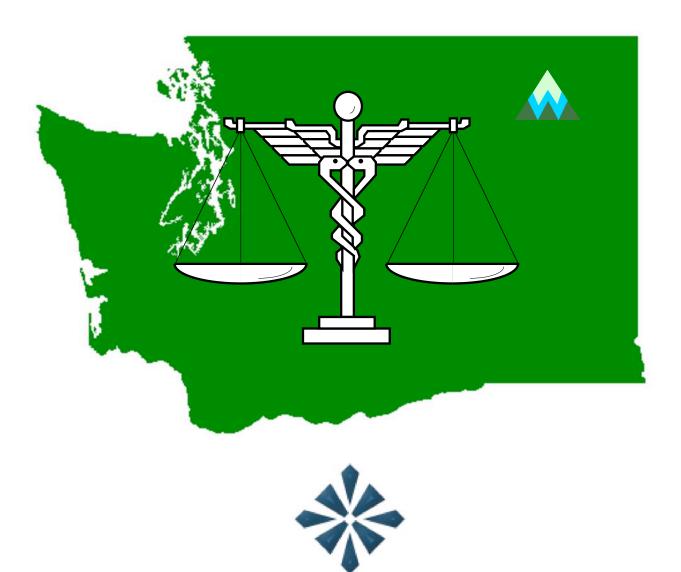
Washington State Certificate of Need Program Task Force Report



September 20, 2006

Materials related to preparation of this Report are available at http://www.hca.wa.gov/conf/ through June 30, 2007

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(cover letter from Cindy and Steve)

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Executive Summary

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(to be completed)

CON Purpose Recommendations

(to be completed)

Review Process Recommendations

(to be completed)

(to be completed)								

Program Operations Recommendations

Context for Certificate of Need

(to be completed)

Washington State Certificate of Need Program Task Force Report

Background

Statutory Guidance

This report is produced as a result of specific legislation passed in the 59th Regular Session of the Washington State Legislature. Engrossed Second Substitute House Bill (ESSHB) 1688 was signed by Governor Gregoire and enacted as Chapter 282, Laws of 2005. In Section 1 of the bill, the Legislature found that:

- (1) Since the enactment of health planning and development legislation in 1979, the widespread adoption of new health care technologies has resulted in significant advancements in the diagnosis and treatment of disease, and has enabled substantial expansion of sites where complex care and surgery can be performed;
- (2) New and existing technologies, supply sensitive health services, and demographics have a substantial effect on health care expenditures. Yet, evidence related to their effectiveness is not routinely or systematically considered in decision making regarding widespread adoption of these technologies and services. The principles of evidence-based medicine call for comprehensive review of data and studies related to a particular health care service or device, with emphasis given to high quality, objective studies. Findings regarding the effectiveness of these health services or devices should then be applied to increase the likelihood that they will be used appropriately;
- (3) The standards governing whether a certificate of need should be granted in RCW 70.38.115 focus largely on broad concepts of access to and availability of health services, with only limited consideration of cost-effectiveness. Moreover, the standards do not provide explicit guidance for decision making or evaluating competing certificate of need applications; and
- (4) The certificate of need statute plays a vital role and should be reexamined and strengthened to reflect changes in health care delivery and financing since its enactment.

Work Groups

Section 2 of ESSHB 1688 created a select Task Force (TF) representative of those with special interest in the Certificate of Need (CON) program, and health care planning and delivery in general. The Legislature specifically directed the TF to study and prepare recommendations to the Governor and the Legislature related to improving and updating the state of Washington CON program described in chapter 70.38 RCW. The TF was further directed to submit its report to the Governor and appropriate committees of the Legislature by November 1, 2006. As specified, TF members were appointed by the Governor and served over a period of 12 months. The names and affiliations of TF members and TF meeting dates appear in Appendix A-1.

Section 2 of the legislation also assigned administration and support of this study to the Washington State Health Care Authority. A budget of \$250,000 was provided in the operating appropriations to the agency [See Engrossed Substitute Senate Bill 6090, Section 213(9), enacted as Chapter 518, Laws of 2005 (partial veto)].

In accordance with Section 2(3), the TF established a Technical Advisory Committee (TAC) to

conduct research, consider stakeholder perspectives and interests, and prepare recommendations to present to the CON Task Force for consideration. The TAC met over a period of eight months. The names and affiliations of TAC members and TAC meeting dates appear in Appendix A-2.

CON Orientation Process

The work of both the TF and the TAC was guided by the following principles outlined in Section 3(1) of ESSHB 1688:

- (a) The supply of a health service can have a substantial impact on utilization of the service, independent of the effectiveness, medical necessity, or appropriateness of the particular health service for a particular individual;
- (b) Given that health care resources are not unlimited, the impact of any new health service or facility on overall health expenditures in the state must be considered;
- (c) Given our increasing ability to undertake technology assessment and measure the quality and outcomes of health services, the likelihood that a requested new health facility, service, or equipment will improve health care quality and outcomes must be considered; and
- (d) It is generally presumed that the services and facilities currently subject to certificate of need should remain subject to those requirements.

The recommendations of the TF were mandated to address at least a specific set of issues outlined in Section 3(2) of ESSHB 1688 as illustrated in Appendix A-3. Thus, the TF sought to make recommendations that would:

- Promote the improvement of quality/outcomes of health care delivered in the state;
- Control the cost of health care delivered in the state; and
- Monitor the outcomes as a result of a revised state health planning and development process.

As background for their deliberations, the TF and the TAC heard from a variety of experts who provided valuable resource and reference information. The history and details of the CON program in Washington is shown in Appendix A-4. Information, as related to CON programs in a cross-section of the 36 other regulated states, is summarized in Appendix A-5. A listing of the presenters from the state of Washington is depicted in Appendix A-6.

Preamble

The TF developed a Preamble as the foundation for the recommendations set forth in this report. This preamble describes compelling factors felt to support the Task Force's recommendations and proposed legislative action to improve and strengthen the Certificate of Need standards and processes in Washington State.

Given that:

- ❖ Health care expenditures are rising at rates substantially above the annual national rate of inflation;
- ❖ Market forces alone in the health care delivery system cannot control health care expenditures;

- ❖ The current structure of the health care financing and delivery system distances the financial burden from the recipients and compromises their ability to make an informed choice;
- ❖ Increasing numbers of citizens are unable to pay for necessary health care because they are uninsured, underinsured, or not eligible for publicly funded programs such as Medicaid and Medicare;
- ❖ Published research supports the existence of a relationship between quality of health care outcomes and volume for providers of selected services;
- Geography, traffic, and population concentrations create barriers to access;
- ❖ Public health issues, disaster preparedness and other emergent health priorities matter and need to be considered in the planning process; and
- Changes in the availability of health care services in a community can have unforeseen consequences.

The Task Force therefore submits the following report and recommendations to improve and strengthen the Certificate of Need Program in RCW 70.38.

Development Process for Recommendations

To best understand the issues, explore options, develop recommendations, and prepare this report, the Task Force used a number of different resources including:

- Input from interested parties at public meetings, and through various correspondences;
- Technical papers on a number of topics related to CON issues and operations;
- Analysis and input from a consultant familiar with CON programs in other states;
- Expert presenters and reports from organizations and interests in the State of Washington and other states regarding their business experience, studies and CON processes;
- Reports from consulting firms on work they were doing in other states and specific issues raised by the Task Force; and
- The JLARC audit recently completed on the Washington State Certificate of Need Program.

The Task Force also considered the suggestions of its TAC. The TAC reviewed existing statutory language; considered additional input and information regarding improvements to the certificate of need program; and proposed new language to the Task Force.

The Task Force considered the TAC proposals and adopted, amended, declined, or returned them to the TAC for further clarification or consideration. Not all TAC proposals are addressed in the Task Force report. The minutes of the Task Force meetings and relevant materials are to be posted through June 30, 2007 on the Health Care Authority website http://www.hca.wa.gov/contf/, and will be archived thereafter.

The final recommendations, as approved by the Task Force are presented in the following sections, with supporting information displayed in the Appendices.

Washington State Certificate of Need Program Task Force Report

Recommendations

Section 3(2) of ESSHB 1688 specifically defined at least six issues to be addressed. Following are the recommendations prepared by the Certificate of Need Task Force in response to the directive:

The task force shall, at a minimum, examine and develop recommendations related to the following issues:

1. Purpose and Goals

ESSHB 1688, Section 3(2) directs the Task Force to undertake:

(b) A review of the purpose and goals of the current certificate of need program, including the relationship between the supply of health services and health care outcomes and expenditures in Washington state;

After much discussion, the Task Force concluded that the CON program would be most effective within the context of a broader state health planning process supported by an adequate data reporting system.

With this perspective, the Certificate of Need Task Force recommends the following conceptual revisions to RCW 70.38.015 (the letters at the left margin denotes existing [**E**], revision to existing [**R**], new [**N**], or [**T**] technical statutory language):

It is declared to be the public policy of this state:

- **R** (1) That a strategic health planning process, responsive to changing health and social needs and conditions, is essential to the health, safety, and welfare of the people of the state, and that it be undertaken biennially by a designated state agency or body:
- E a) To promote, maintain, and assure the health of all citizens in the state;
- T b) To provide accessible health services, health workforce, health facilities, and other resources;
- T c) To control excessive increases in costs:
- N d) To apply specific quality criteria and population health indicators;
- N e) To recognize prevention as a high priority in health programs;
- N f) To address periodic priority issues including disaster planning, public health threats, public safety dilemmas, and others; and
- N g) To coordinate efforts among state agencies including facility, services and professional provider licensure; state and federal reimbursement; health service utilization data systems; and others;
- **R** (2) That both consumers and providers throughout the state shall be involved in this health planning process, outcomes of which shall be clearly articulated and available for public review and use;

- **N** (3) That the certificate of need program is a component of a health planning regulatory process that:
- **N** a) Contributes to state health plan and public policy goals that are:
 - i) Clearly articulated, and
 - ii) Regularly updated;
- **R** b) Balances considerations of:
 - i) Access to quality care at a reasonable cost for all residents,
 - ii) The optimal use of existing health care resources,
 - iii) Fostering of expenditure control, and
 - iv) Unnecessary duplication of health care facilities and services;
- N c) Supports improved health care outcomes by:
 - i) Basing decisions on the best available evidence and information, and
 - ii) Continuously monitoring compliance;
- N d) Is accountable for maintaining the resources necessary for quality, timely, and consistent decisions; and
- N e) Regularly evaluates the impact of capacity management on health services expenditures, access, quality, and innovation;
- **R** (4) That the development and ongoing maintenance of adequate health care information, statistics, and projections of need for health facilities and services is essential to effective health planning and resources development; at a minimum, the data system shall support the review and monitoring of the specified health care facilities and services regulated by the certificate of need program;
- **R** (5) That the development of other approaches to health care expenditure control shall be considered, including the strengthening of competition; and
- **R** (6) That strategic health planning shall be concerned with the stability of the health system, encompassing health care financing, quality, and the availability of information and services for all residents.

A detailed table showing the Task Force's worksheet is illustrated in Appendix C-1 (RCW 70.38.015 subsections 1, 2, 3, 4, 5, 6).

2. Criteria for Review of CON Applications

ESSHB 1688, Section 3(2) directs the Task Force to examine:

- (d) The criteria for review of certificate of need applications, as currently defined in RCW 70.38.115, with the goal of having criteria that are consistent, clear, technically sound, and reflect state law, including consideration of:
 - (i) Public need for the proposed services as demonstrated by certain factors, including, but not limited to:
 - (A) Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;

- (B) Whether the project will have a positive impact on the health status indicators of the population to be served;
- (C) Whether there is a substantial risk that the project would result in inappropriate increases in service utilization or the cost of health services;
- (D) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
- (E) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project, including whether there is data to indicate that the proposed health services would constitute innovations in high quality health care delivery;
- (ii) Impact of the proposed services on the orderly and economic development of health facilities and health resources for the state as demonstrated by:
 - (A) The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
 - (B) The impact of the project on the ability of existing affected providers and facilities to continue to serve uninsured or underinsured residents of the community and meet demands for emergency care;
 - (C) The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and
 - (D) The likelihood that more effective, more accessible, or less costly alternative technologies or methods of service delivery may become available;

After considering existing criteria for CON application review, the Task Force modified and expanded the analytical provisions and added new criteria. The Task Force recommends that these criteria be updated at least every two years.

The Task Force recommends stronger connections between CON and licensure of health care facilities and providers. Better communication would enable the Department of Health to improve its monitoring and enforcement of CONs issued with certain understandings or conditions through the licensing process. Similarly, the Task Force recommends that CON decisions be more closely connected with charity care obligations of health care facilities and providers, as may be applicable. Understanding that charity care obligations apply at this time only to hospitals, the Task Force recommends conceptual language in RCW 70.38.115(2)(l) to expand consideration of charity care programs and activities to other health care entities and providers.

To improve the review criteria, the Certificate of Need Task Force specifically recommends the following conceptual revisions to RCW 70.38.115 (the letters at the left margin denote existing [E], revision to existing [R], new [N], or [T] technical changes to statutory language) knowing that operational details will be developed as rules (WAC) by the department responsible for Certificate of Need activities:

R (1) Certificates of need shall be issued, denied, suspended, or revoked by the designee of the secretary in accord with the provisions of this chapter and rules of the department that develops review criteria and establishes review procedures.

- E (2) Criteria for the review of certificate of need applications, except as provided in subsection (3) of this section for health maintenance organizations, shall include but not be limited to consideration of the following:
- **R** (a) Community need for the proposed services, based on current utilization data and trends;
- **E** (b) The availability of less costly or more effective alternative methods of providing such services:
- **R** (c) The financial feasibility and the probable impact of the proposal on the cost of and charges for providing health services in the community to be served, including the impact on the current health system infrastructure and ability of existing providers to serve the under-insured and uninsured;
- **R** (d) In the case of health services to be provided,
 - (i) the availability of alternative uses of project resources for the provision of other health services,
 - (ii) the extent to which such proposed services will be accessible to all residents of the area to be served, and
 - (iii) the need for and the availability in the community of services and facilities for health care providers and their patients. The department shall consider the application in terms of its impact on existing and proposed institutional and other educational training programs for health practitioners at the student, internship, and residency training levels;
- E (e) In the case of a construction project, the costs and methods of the proposed construction, including the cost and methods of energy provision, and the probable impact of the construction project reviewed
 - (i) on the cost of providing health services by the person proposing such construction project and
 - (ii) on the cost and charges to the public of providing health services by other persons;
- **R** (f) The special needs and circumstances of children's hospitals:
- N (g) The needs of special populations;
- T (h) Improvements or innovations in the financing and delivery of health services that foster cost containment and serve to promote quality assurance and cost-effectiveness:
- T (i) For health services proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed;
- T (j) For existing services or facilities, the quality of care provided by such services or facilities in the past;
- **R** (k) In the case of hospitals, whether the applicant meets or exceeds the regional average level of charity care, as determined by the secretary, and whether the applicant has adopted policies consistent with the charity care and reporting requirement of RCW 70.170.060;
- N (1) For other CON regulated services, whether the applicant has made provisions for charity care commensurate with current community standards for the service(s) to be offered:
- N (m) The availability of appropriate health care workers to deliver the proposed service; and

- N (n) Whether the applicant agrees to provide services to Medicaid and Medicare enrollees and agrees to not discriminate against Medicaid and Medicare enrollees based upon their coverage.
- E (3) A certificate of need application of a health maintenance organization or a health care facility that is controlled, directly or indirectly, by a health maintenance organization, shall be approved by the department if the department finds:
- **E** (a) Approval of such application is required to meet the needs of the members of the health maintenance organization and of the new members which such organization can reasonably be expected to enroll; and
- E (b) The health maintenance organization is unable to provide, through services or facilities which can reasonably be expected to be available to the organization, its health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the organization and which makes such services available on a long-term basis through physicians and other health professionals associated with it.
- E A health care facility, or any part thereof, with respect to which a certificate of need was issued under this subsection may not be sold or leased and a controlling interest in such facility or in a lease of such facility may not be acquired unless the department issues a certificate of need approving the sale, acquisition, or lease.
- **R** (4) The decision of the department on a certificate of need application shall be consistent with a state health plan that is updated at least biennially, except in emergency circumstances that pose a threat to the public health. The department in making its final decision may issue a conditional certificate of need if it finds that the project is justified only under specific circumstances. The conditions shall directly relate to the project being reviewed. The conditions may be released if it can be substantiated that the conditions are no longer valid and the release of such conditions would be consistent with the purposes of this chapter.
- **R** (5) Criteria adopted for review in accordance with subsection (2) of this section may vary according to the purpose for which the particular review is being conducted or the type of health service reviewed. Criteria, standards, and methods for determining need shall be reviewed and updated at least biennially after consultation with a technical advisory committee.

A detailed table showing the Task Force's worksheet is illustrated in Appendix C-4 (RCW 70.38.115 subsections 1, 2, 3, 4, 5).

3. Scope of Services and Facilities Subject to CON Review

ESSHB 1688, Section 3(2) directs the Task Force to examine:

- (c) The scope of facilities, services, and capital expenditures that should be subject to certificate of need review, including consideration of the following:
 - (i) Acquisitions of major medical equipment, meaning a single unit of medical equipment or a single system of components with related functions used to provide medical and other health services;

- (ii) Major capital expenditures. Capital expenditures for information technology needed to support electronic health records should be encouraged;
- (iii) The offering or development of any new health services, as defined in RCW 70.38.025, that meets any of the following:
 - (A) The obligation of substantial capital expenditures by or on behalf of a health care facility that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the health care facility within the twelve-month period prior to the time the services would be offered;
 - (B) The addition of equipment or services, by transfer of ownership, acquisition by lease, donation, transfer, or acquisition of control, through management agreement or otherwise, that was not offered on a regular basis by or on behalf of the health care facility or the private office of a licensed health care provider regulated under Title 18 RCW or chapter 70.127 RCW within the twelve-month period prior to the time the services would be offered and that for the third fiscal year of operation, including a partial first year following acquisition of that equipment or service, is projected to entail substantial incremental operating costs or annual gross revenue directly attributable to that health service;
- (iv) The scope of health care facilities subject to certificate of need requirements, to include consideration of hospitals, including specialty hospitals, psychiatric hospitals, nursing facilities, kidney disease treatment centers including freestanding hemodialysis facilities, rehabilitation facilities, ambulatory surgical facilities, freestanding emergency rooms or urgent care facilities, home health agencies, hospice agencies and hospice care centers, freestanding radiological service centers, freestanding cardiac catheterization centers, or cancer treatment centers. "Health care facility" includes the office of a private health care practitioner in which surgical procedures are performed;

The Task Force concluded that specific descriptive criteria were needed to evaluate whether additional health care facilities, major medical equipment and health services would require CON review. This Task Force recommendation related to scope of coverage is based on an examination of the facilities and services currently subject to CON review. It also considered new criteria, clarifying information and other recommendations presented by the Technical Advisory Committee (see Appendix B-1) as well as comments from various stakeholders and Task Force members.

The Task Force recommends that, if one or more of the following conditions exist, a health care facility, equipment or service be added to the current listing of items subject to CON review:

- 1. Tertiary services whose clinical quality and/or cost effectiveness is directly and demonstrably tied to volume, including high-risk tertiary services that require complex multi-specialty interactions.
- 2. New, additional or changed services that may have a significant adverse impact on the existing health delivery systems' ability to continue to provide essential services to all residents in an economically feasible manner, or may impose significant barriers to access.
- 3. New or existing health care facility, service, or major medical equipment for which there is inconsistent state regulation based on ownership or Medicare certification.
- 4. Emerging or existing devices, technology and services for which clinical efficacy and patient safety have not been fully established.

5. Emerging or existing devices, technology and services for costly procedures whose appropriate utilization has not been established, and for which there is a risk of inappropriate utilization.

The Task Force concluded that these criteria be applied to health care facilities, equipment, and services in order to update the scope of CON review. The Task Force applied these criteria and, on that basis, recommends the following modifications to the current scope of facilities, equipment and services subject to CON review. These recommendations are presented in four categories:

- Proposed for No Review: items that would not require CON examination;
- *Proposed for Continued Review:* items that are currently reviewed by CON in the State of Washington, and would proceed without change;
- *Proposed for New Review:* items not currently reviewed by CON, but are recommended to be added to the list of those items currently reviewed using the definition above; and
- *Proposed for Future Study:* items that have been suggested for potential new review, but require additional evaluation before a decision be made.

Appendix B-2 recaps the Task Force recommendations. Appendix B-3 is the worksheet used by the Task Force to determine whether CON review for the new items is appropriate under the recommended updated criteria. Appendices C-2 (RCW 70.38.025 subsections 6, and new) and C-3 (RCW 70.38.105 subsection 4 and new) are the Task Force's worksheets that provide examples of how these conceptual recommendations could be applied to existing statutes.

Proposed for No Review

Long Term Care

Boarding homes (assisted living facility)
Specialty care assisted living facility
Intermediate care mentally retarded facility
Residential care facility
Psychiatric residential treatment facility
Adult family homes

Medical Equipment

Hyperbaric chambers Ultrasound Heart-lung bypass machines Computed tomography scanners

Outpatient Services

Behavioral health services Opiate replacement treatment facilities (methadone) Urgent care facilities Substance abuse services Community clinic

Procedures

Primary/emergent angioplasty

Lithotripsy

Other Services

Information technology needed to support electronic health records Medical office buildings Birthing centers

Proposed for Continued Review

(NOTE: Some items were evaluated pursuant to ESSHB 1688 direction, but are already reviewed as part of CON hospital review.)

Acute Inpatient

Substance abuse (adult, part of hospital review)

Substance abuse (child/adolescent - part of hospital review)

Intensive care unit (ICU)/critical care unit (part of hospital review)

Adult ICU (part of hospital review)

Medical-surgical licensed beds

Rehabilitation (Level I)

Psychiatric (licensed)

Obstetrics (Levels II & III)

Pediatrics (specialty) includes ICU

Neonatal ICU (Levels II & III)

Burn units (specialty)

Specialty hospitals (heart, orthopedic, surgical)

Long Term Care

Subacute care (Medicare distinct part)

Long term care hospital

Nursing homes

Continuing care retirement center (5-year Medicaid life care requirement)

Swing beds (>5 beds)

Procedures

Therapeutic cardiac catheterization

Elective angioplasty

Kidney treatment centers (including hemodialysis)

Surgery

General inpatient (part of hospital review)

Hospital outpatient (part of hospital review)

Hospital-based ambulatory surgery center (part of hospital review)

Open heart (adult)

Open heart (pediatric)

Solid organ transplant (adult)

Solid organ transplant (pediatric)

Bone marrow/stem cell transplants

Freestanding ambulatory surgery centers open to non-owner practitioners

Other Services

Home health care (Medicare/Medicaid eligible)

Hospice care centers (inpatient)
Hospice agencies (outpatient, Medicare/Medicaid)

Proposed for New Review

(NOTE: See Appendix B-3 for Task Force rationale supporting recommendations.)

Medical Equipment

Cyber knives

Gamma knives

Positron emission tomography scanners

Positron emission tomography/computed tomography scanners

Linear accelerators

Robotic surgery

Outpatient services

Freestanding emergency departments

Freestanding radiological service centers

Diagnostic imaging centers

Oncology (cancer) treatment centers

Surgery

Cardiac surgery suites (outpatient and not done under a hospital license)

All ambulatory surgery centers regardless of owner or operator

(NOTE: The current rule provides an exemption for single-specialty freestanding ambulatory surgery centers restricted to owner practitioners.)

Proposed for Future Study

Acute Inpatient

Conversion of acute care bed type

Long Term Care

Conversion of long term care bed type

Medical Equipment

Magnetic resonance image scanners

Procedures

Diagnostic cardiac catheterization

Surgery

Physician practice office-based surgery

Other Services

Research and demonstration projects

Air ambulance

Home health care (regardless of payment source)

Hospice agencies (regardless of payment source)

The Task Force also recommends that financial review thresholds not be applied to any facilities, equipment and services not listed above. The Task Force concluded that the existing and new

criteria (not merely the financial cost) serve to determine whether a facility, equipment or service be subject to CON review.

4. New and Updated Service and Facility Specific Policies

ESSHB 1688, Section 3(2) directs the Task Force to examine:

(a) The need for a new and regularly updated set of service and facility specific policies that guide certificate of need decisions;

After examining these policies, the Task Force expanded the public policy list to address concerns about measures, information and accountability of CON decisions making. The Task Force recommends that these policies be updated at least every two years.

To clarify and improve the policies that guide CON decisions, the Task Force specifically recommends the following conceptual revisions to RCW 70.38.015 (the letter at the left margin denotes new [N] statutory language) be added to those already proposed in the section on Purpose and Goals. The Task Force assumes that operational details will be developed as rules (WAC) by the department responsible for Certificate of Need activities:

- E It is declared to be the public policy of this state:
- **N** (3) That the certificate of need program is a component of a health planning regulatory process that:
- N f) Utilizes detailed criteria, standards and need methodologies, both general and service/facility specific, that are updated at least biennially after consultation with a Technical Advisory Committee; and
- N g) Is conducted in a transparent and accountable manner.

A detailed table illustrating the Task Force's worksheet is contained in Appendix C-1 (RCW 70.38.015 subsection 3).

5. Mechanisms to Monitor Ongoing Compliance

ESSHB 1688, Section 3(2) directs the Task Force to examine:

(f) Mechanisms to monitor ongoing compliance with the assumptions made by facilities that have received either a certificate of need or an exemption to a certificate of need, including those related to volume, the provision of charity care, and access to health services to medicaid and medicare beneficiaries as well as underinsured and uninsured members of the community.

The Task Force considered both statutory and rule modifications, and was guided by the Department of Health's analysis of the appropriate mechanism for each issue. The Task Force recommends the following modifications:

Statutory Modification Recommendation – related to funding, data and compliance

- (1) Application fees and other sources of revenue that are sufficient to cover the specific or direct costs of CON application review and monitoring and other related costs and systems, e.g. data systems be established.
- (2) The data for CON analysis and monitoring be a subset of a comprehensive data system for state health planning that includes improved data collection methods and reporting consistent with technological advances.
- (3) The state collect and report CON data on an ongoing basis using consistent and reliable performance measures.
- (4) Data regarding CON reviewable services include:
 - a. Comprehensive inpatient and outpatient data, and
 - b. Financial and utilization information related to charity care, quality, and cost regardless of the service location.
- (5) Data be publicly available for applicants and observers.
- (6) Data collected in this process may produce indications for quality and performance improvement to be reported to the state planning body and all other appropriate agencies.
- (7) The length of compliance accountability and oversight be extended to at least five years after project completion.
- (8) Penalties for non-compliance with provisions and conditions of the CON-approved application be created and enforced. Examples of appropriate penalties include revocation of the CON award and fines.

Detailed tables showing the Task Force's worksheets are provided in Appendices C-3 (RCW 70.38.105 new subsection), C5 (RCW 70.38.125 subsection 3 and new), C-6 (RCW 70.38.135 subsection 3), and C-7 (RCW 43.70.052 new subsection).

Rule Recommendations – related to communication and monitoring

- (1) Maintain communication between affected state agencies to permit cross-check between licensing, certification, registration and/or reimbursement sources that would support compliance monitoring related to the approved scope of services.
- (2) Retain current process of periodic progress reports after decision until the service becomes operational, followed by documentation of completed costs.
- (3) Monitor the provision of the approved service:
 - a. Consistent with the assumptions that led to approval;

- b. To the population promised;
- c. At the promised level of charity care;
- d. In compliance with added conditions;
- e. Observing the utilization/volume standards appropriate in tertiary services (or demonstrating that departure from the assumptions is reasonable [evidence-based wherever possible] and has not negatively affected outcomes); and
- f. Attaining the "special conditions/representations" that resulted in the decision to award.
- (4) Expand monitoring systems as data capabilities develop or permit.

Additional Recommendations – related to licensure, certification and data

Because of the close link between the purposes of state licensure and CON review, the Task Force recommends that all CON-reviewed items be either licensed or certified by the state of Washington, and that operational data systems be developed and linked to licensure and certification.

6. Program Processes

ESSHB 1688, Section 3(2) directs the Task Force to examine:

(e) The timeliness and consistency of certificate of need reviews and decisions, the sufficiency and use of resources available to the department of health to conduct timely reviews, the means by which the department of health projects future need for services, the ability to reflect differences among communities and approaches to providing services, and clarification on the use of the concurrent review process; and

The Task Force considered both statutory and rule modifications, and was guided by the Department of Health's analysis of the appropriate mechanism for each issue. The Task Force recommends the following modifications:

Statutory Modification Recommendation – related to operational improvement and transparency

- (1) Use expedited and/or abbreviated cycles for applications that comply with the state health plan and have minimal impact on area health services.
- (2) Invite CON proposals based on service needs that are determined by the state health plan.
- (3) Use evidence-based health care criteria and standards consistent with the state health plan that are updated at least biennially.

A detailed table showing the Task Force's worksheet is provided in Appendix C-6 (RCW 70.38.135 subsection 3 and new).

Rule Recommendations – related to process and transparency

- (1) Maintain the current process flow of staff screening followed by public comment, with a final decision by the Secretary of the Department of Health or her/his designee.
- (2) Continue to obtain quality, access, and utilization data, as well as licensure information from other state agencies, as it relates to CON applications/applicants.
- (3) Retain the current methodology for defining service areas.
- (4) Maintain the mechanism for notifying the public of Letters of Intent and the receipt of applications, which may trigger submission of competing applications.
- (5) Continue to batch competing applications for similar service types and geographic areas into concurrent review cycles.
- (6) Assure that the burden of proof is on the applicant to provide documentation of community need and detailed responsiveness to CON criteria and standards.
- (7) Assure the availability of sufficient resources (including staff with technical expertise).
- (8) Provide a timely, accountable, and reasonable process in compliance with existing statutes/rules.
- (9) Assure consistency of review with reliability across analysts.
- (10) Through rule making, create a more efficient and transparent application process.
- (11) Through rule making, address and create criteria for making tie-breaking decisions between two or more appropriate and equivalent applications.
- (12) Use electronic applications, processing, and reporting for public transparency, accountability, and public input.
- (13) Provide transparency during all phases of the CON process (screening by staff, post-analysis by staff, pre-public comment, and post-public comment) of data related to:
 - a. Volumes,
 - b. Application types,
 - c. Appeals or resolutions,
 - d. Denials.
 - e. Compliance, and
 - f. Other related application data and information.

The Task Force reviewed the Performance Audit of the Certificate of Need Program from the Joint Legislative Audit and Review Committee, and used their six recommendations as a reference tool in the preparation of these recommendations (see Appendix D-1).

7. Other Issues of Concern

ESSHB 1688, Section 3(2) directs the Task Force to examine and develop recommendations related to, at minimum, a specific set of issues. After much discussion, the TF concluded that the CON program would be most effective within the context of a broader state health planning process supported by an adequate data reporting system. The issue of health planning stood out above all others as requiring special emphasis and elaboration.

State Health Plan

The CON process was originally designed within the context of a formal state health planning process. Need determinations for services and facilities that drove CON decisions emanated from the state health plan. However, Washington's health plan has not been updated since 1987. Thus, the current CON program operates in a planning vacuum, with no formal state health plan to guide its need determinations and its decisions. The Task Force repeatedly observed that the lack of a state health plan compromised the CON program's ability to achieve its goals – or even to articulate what its goals should be.

Thus, the Task Force recommends that the state reenergize its formal health planning process, create a state health plan, and update it biennially. Based on a review of health plans in several other states, the Task Force recommends that the following seven components be included in Washington's state health plan:

- Rationale including vision, purpose, mission, and principles;
- Participants including state agencies, providers, purchasers, consumers, and advocates;
- Existing system including health status, inventory facilities/equipment/services, and data;
- **Proposed description** of health system at a given planning horizon;
- Action planning including goals, objectives, criteria, standards, priorities, and strategies;
- Evaluation including monitoring, data reporting, feedback, and updating; and
- Appendices including planning areas, acronyms, references, and others.

Appendix B-4 provides samples of the tables of contents from several state health plans, including Washington's 1987 plan. A synthesis of samples has also been provided to capture some of the important features of each.

With this perspective, the Task Force recommends the following conceptual revisions relating to a state health plan, in addition to the recommended conceptual revisions made in the section on Purpose and Goals:

- (1) To recognize the close interrelationship of health planning concerns and emphasize health care expenditure control, including cost-effectiveness and cost-benefit analysis;
- (2) To integrate criteria for evidence-based medicine into the process;

- (3) To invite proposals for CON in response to service needs determined by the state health plan; and
- (4) To use expedited and/or abbreviated cycles for applications that comply with the state health plan and have minimal impact on area health services.

A detailed table illustrated in Appendix C-1 (RCW 70.38.015 subsections 1 and 3).



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Washington State Certificate of Need Program Task Force Report

Appendices

Background



Appendix A-1 Task Force Composition and Meetings

			Meetings												
Member Name	Representing:	F: face-to-face T: telephone conference call													
		F: 10/06/05	T: 10/19/05	$\ddot{\vdash}$	Ŀ.	F: 01/03/06	T: 01/25/06	T: 02/08/06	T: 03/06/06		F: 05/17/06	T: 06/14/06		F: 08/16/06	F: 10/11/06
Rep. Barbara Bailey (R)	Legislator Representative, House Health Care Committee	X			X	X			led	Y		X		X	
Norman Charney, MD	Private Employer-Sponsored Health Benefits Purchaser Representative	X	X	X	X	X	X	X	car	X	X		X		
Rep. Eileen Cody (D)	Legislator Representative, Chair, House Health Care Committee	X			X	X			meeting	X	X		X	X	
Sen. Alex Deccio (R)	Legislator Representative, Ranking Republican, Senate Health & Long Term Care Committee		X				X	X							
Dorothy Graham	Private Employer-Sponsored Health Benefits Purchaser Representative		X	X	X	X	X	X		X		X	X	X	
Steve Hill	Administrator, Health Care Authority	X	X	X	X	X	X	X		X	X		X	X	
Denise Hopkins, DDS	Health Care Consumer Representative	X						X			X			X	
Kathy Marshall	Division Director, Aging and Disability Services Administration, Department of Social and Health Services	X	X	X	X	X	X			X	X	X	X	X	
Palmer Pollock	Health Care Provider Representative				X	X	X	X		X			X	X	
Mary Selecky	Secretary, Department of Health		X	X	X X	X X	X	X		X	X X	X X	X	X X	
Jon Smiley	Health Care Provider Representative				X	X		X		X	X	X		X	
Robby Stern	Labor Representative, (Taft- Hartley Plan)		X	X	X	X	X			X	X		X	X	
Sen. Pat Thibaudeau (D)*	Legislator Representative, Vice Chair, Senate, Health & Long Term Care Committee	X		X	X										
Janet Varon	Health Care Consumer Representative	X	X	X							X		X		
Carolyn Watts, PhD	Health Care Economist Representative		X					X		X	X				
Rick Woods	Health Carrier Representative	X	X	X	X	X	X				X	X	X	X	

^{*}resigned from Task Force due to conflicting schedule

Appendix A-2 Technical Advisory Committee Composition and Meetings

				Me	etir	ıgs				
Member Name	Representing:	F: face-to-face T: telephone conference call								
		X F: 11/17/05	F: 12/13/05	X F: 02/16/06	F: 03/16/06	F: 04/13/06	X F: 05/25/06	90/80/90 X		
Jody Carona	Consultant, Health Facilities Planning and Development	X	X	X	X		X	X		
Scott Norris Faringer	Administrator, Yakima Ambulatory Surgical Center		X							
Donna Goodwin	Vice President of Operations, Family Home Care		X		X	X	X	X		
William Hagens	Clinical Professor, University of Washington School of Public Health and Community Medicine, Member, State Nursing Care Quality Assurance Commission	X	X	X			X	X		
Eleanor Hamburger	Attorney, Siranni, Youtz, Meier and Spoonemore	X	X	X		X	X	X		
Debra Hatfield*	Consumer, King County American Heart Association	X								
Michael Kelly, MD*	Nephrologist, Minor & James Clinic		X							
Jean Pfeifer, RN, BSN	Staff Nurse/NICU, Children's Hospital	X	X	X	X	X	X			
Palmer Pollock	Planning Administrator, Northwest Kidney Centers	X	X	X	X		X	X		
Gil Rodriguez, MD	Anesthesiologist, Chief Medical Officer/VP Marketing and Planning, Southwest Washington Medical Center	X		X	X		X			
Simeon Rubenstein, MD	Cardiologist, Group Health Cooperative, Clinical Professor /Cardiology, University of Washington School of Medicine	X	X		X	X				
Scott Scherer*	Vice President and General Manager, Aircraft Financial Services, Boeing									
Sue Sharpe Jon Smiley	Health Planning Consultant CEO,	X	X X	X	X	X	X	X X		
Lloyd Lee Smith*	Sunnyside Community Hospital Chief Operating Officer, Spokane County Health District		1	71				1		

^{*}resigned from Technical Advisory Committee due to conflicting schedules

Appendix A-3 ESSHB 1688 Issues to Be Addressed

(Editor's Note: indenting applied to improve readability, original has even left margin)

Section 3(2) The task force shall, at a minimum, examine and develop recommendations related to the following issues:

- (a) The need for a new and regularly updated set of service and facility specific policies that guide certificate of need decisions;
- (b) A review of the purpose and goals of the current certificate of need program, including the relationship between the supply of health services and health care outcomes and expenditures in Washington state;
- (c) The scope of facilities, services, and capital expenditures that shall be subject to certificate of need review, including consideration of the following:
 - (i) Acquisitions of major medical equipment, meaning a single unit of medical equipment or a single system of components with related functions used to provide medical and other health services;
 - (ii) Major capital expenditures. Capital expenditures for information technology needed to support electronic health records shall be encouraged;
 - (iii) The offering or development of any new health services, as defined in RCW 70.38.025, that meets any of the following:
 - (A) The obligation of substantial capital expenditures by or on behalf of a health care facility that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the health care facility within the twelve-month period prior to the time the services would be offered;
 - (B) The addition of equipment or services, by transfer of ownership, acquisition by lease, donation, transfer, or acquisition of control, through management agreement or otherwise, that was not offered on a regular basis by or on behalf of the health care facility or the private office of a licensed health care provider regulated under Title 18 RCW or chapter 70.127 RCW within the twelve-month period prior to the time the services would be offered and that for the third fiscal year of operation, including a partial first year following acquisition of that equipment or service, is projected to entail substantial incremental operating costs or annual gross revenue directly attributable to that health service:
 - (iv) The scope of health care facilities subject to certificate of need requirements, to include consideration of hospitals, including specialty hospitals, psychiatric hospitals, nursing facilities, kidney disease treatment centers including freestanding hemodialysis facilities, rehabilitation facilities, ambulatory surgical facilities, freestanding emergency rooms or urgent care facilities, home health agencies, hospice agencies and hospice care centers, freestanding radiological service centers, freestanding cardiac catheterization centers, or cancer treatment centers. "Health care facility" includes the office of a private health care practitioner in which surgical procedures are performed;
- (d) The criteria for review of certificate of need applications, as currently defined in RCW 70.38.115, with the goal of having criteria that are consistent, clear, technically sound, and

reflect state law, including consideration of:

- (i) Public need for the proposed services as demonstrated by certain factors, including, but not limited to:
 - (A) Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;
 - (B) Whether the project will have a positive impact on the health status indicators of the population to be served;
 - (C) Whether there is a substantial risk that the project would result in inappropriate increases in service utilization or the cost of health services:
 - (D) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
 - (E) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project, including whether there is data to indicate that the proposed health services would constitute innovations in high quality health care delivery;
- (ii) Impact of the proposed services on the orderly and economic development of health facilities and health resources for the state as demonstrated by:
 - (A) The impact of the project on total health care expenditures after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
 - (B) The impact of the project on the ability of existing affected providers and facilities to continue to serve uninsured or underinsured residents of the community and meet demands for emergency care;
 - (C) The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and
 - (D) The likelihood that more effective, more accessible, or less costly alternative technologies or methods of service delivery may become available;
- (e) The timeliness and consistency of certificate of need reviews and decisions, the sufficiency and use of resources available to the department of health to conduct timely reviews, the means by which the department of health projects future need for services, the ability to reflect differences among communities and approaches to providing services, and clarification on the use of the concurrent review process; and
- (f) Mechanisms to monitor ongoing compliance with the assumptions made by facilities that have received either a certificate of need or an exemption to a certificate of need, including those related to volume, the provision of charity care, and access to health services to medicaid and medicare beneficiaries as well as underinsured and uninsured members of the community.

Appendix A-4 State of Washington Orientation Materials

Copies of these materials are available on the Health Care Authority website at http://www.hca.wa.gov/contf/index.shtml

• Washington CON History:

Department of Health (DOH) representatives Janis Sigman, Gary Bennett, Bart Eggan, and Byron Plan provided a detailed presentation of significant events from the 1971 initiation of the state of Washington CON program through 2004, as well as described the licensure process and non-hospital surgical setting issues. Supporting presentation materials prepared by DOH included:

- <u>CON History</u>: a six-slide Power Point presentation covering an annotated period of Washington CON milestones from 1971-2004
- <u>Health Planning</u>: a one-page description of the 1971 CON authorization and initial health planning, including the State Health Coordinating Council and Health Systems Agencies
- <u>CON Basic</u>: a three-page overview of the Washington CON program, what it reviews, its general review criteria, statutes, and rules, plus contact information
- <u>CON Coverage Comparison Pre-1989 Today</u>: a three-page table comparing the services and facilities reviewed before and after 1989, a point of significant regulatory reduction
- <u>CON Concurrent Review Cycles</u>: a two-page table comparing the review cycles, letter of intent due dates, and other deadline information about each service and facility grouping
- <u>CON Timeline</u>: a two-page table illustrating the timelines for CON applications undergoing CON review including regular, expedited, and concurrent reviews
- <u>10-year Decision Charts</u>: a 12-page set of graphic representations of the number of CON applications approved and denied presented by types of service or facility
- <u>A Statewide Assessment of Health Status, Health Risks, and Health Care Services</u>: a link to the 129-page 2004 Supplement of "The Health of Washington State"
- <u>Washington State Health Report:</u> a link to the annual 2004 Washington State Health Report which is a guide for preparing agency budget and legislation for 2005-2007

Joyce Stockwell from the Department of Social and Health Services also described long-term care and licensure activities during the same period.

• Certificate of Need Study - Phase I:

Mercer Human Resource Consulting submitted a report on August 18, 2005, that summarized the purpose of CON, outlined the findings of the CON assessments since 1999 - specifically, the impacts of cost, access, quality, and technology - and provided conclusions and suggestions for Phase II of the Washington CON project. The processes employed by other states in implementing their CON requirements and procedures were also reported in this paper's appendices.

• State of Washington Joint Legislative Audit and Review Committee (JLARC):

Report-1 *Effects of Certificate of Need and Its Possible Repeal* was prepared by the Health Policy Program of the University of Washington's School of Public Health and Community Medicine for JLARC and released on January 8, 1999. The study found that CON had not controlled overall health care spending or hospital costs. The study further found conflicting or limited evidence about: the effects of CON on the quality and availability of other health care services, and the effects of repealing CON. Three policy options were presented for consideration:

- (1) Reform CON to address its current weaknesses;
- (2) Repeal parts or all of the program while taking steps to increase monitoring and ensure that relevant goals are being met; and
- (3) Conduct another study to identify more clearly the possible effects of repeal in Washington State.

JLARC was mandated by ESSHB 1688 to conduct a performance audit of the Department of Health's administration and implementation of its CON program. The study objectives included the following questions:

- How does DOH evaluate CON applications (are decisions consistent with statute, and what data and analysis does DOH use)?
- Are decisions consistent with each other?
- How does DOH measure the performance of the CON program?
- How does DOH monitor CON projects?

• State Health Plan:

The last Washington State Health Plan is an 853-page document produced December 30, 1980. A 378-page Part II was released in 1982. Two addendums were added in 1987: Volume 1: Health Principles, Goals, and Strategies (54 pages) and Volume 2: Performance Standards for Health Facilities and Services (122 pages). No updates to this Plan have been released since May 12, 1987.

• Governor Christine O. Gregoire:

Steve Hill, as the delegate of Governor Gregoire, articulated the Governor's state health care priorities in presenting the following Five-point Strategy for Improving Health Care in her Policy Brief called "Raising the Bar for Health Care":

- Emphasize evidence-based health care
- Promote prevention, healthy lifestyles and healthy choices
- Better manage chronic care
- Create more transparency in the health care system
- Make better use of information technology

Appendix A-5 National Experience Orientation Materials

Copies of these are available on the HCA website at http://www.hca.wa.gov/contf/index.shtml

• CON National Experience:

Thomas R. Piper of MacQuest Consulting provided numerous descriptions of the 37 diverse CON programs in the United States, including:

- National CON Perspective and Experience: "Key State" Comparisons
- Selected Review of State Public Oversight Efforts
- 2005 Relative Scope and Review Thresholds: CON Regulated Services by State
- Elements of Effective Regulation
- State Responses About CON Monitoring and Data
- National Directory of Health Planning, Policy, and Regulatory Agencies 2005

• CON Health Care Policy Programs:

- A review of Certificate of Need Health Care Policy Programs: At the Intersection of Science and Politics: a 31-slide Power Point by Bruce Spector, Esq., from Vermont
- <u>The Precarious Pricing System For Hospital Services</u>: a link to the research article by Christopher P. Tompkins, Stuart H. Altman, and Efrat Eilat, *Health Affairs*, Vol. 25, No. 1, January/February 2006, p.45, (DOI 10.1377/hlthaff.25.1.45)
- <u>Failure of Government Central Planning: Washington's Medical Certificate of Need Program</u>: a link to a large multi-page January 2006 article by John Barnes, Policy Analyst at the *Washington Policy Center*

• Vermont Experiences:

Bruce Spector, Esq., from the State of Vermont provided significant CON descriptions based on his Vermont experience, including:

- Health Resource Allocation Plan
- Vermont CON Reform Law
- Vermont HRAP: Section Four, CON Standards

• Michigan and Business Experiences:

Renee Turner-Bailey, MHSA, presented a series of CON descriptions based on her CON Commission and automakers experience in Michigan, as well as her involvement in the National Quality Forum, Leapfrog, and other participation, including:

- Overview of Compliance Monitoring Options and Opportunities
- Health Care Quality Efforts in the U.S. An Employer's Perspective

• Specialty Hospitals:

- <u>Do Specialty Hospitals Promote Price Competition?</u>: a link to small multi-page Issue Brief No. 103 from the *Center for Studying Health System Change* by Robert A. Berenson, Glaria J. Bazzolit, and Melanie Au, January 2006

• FTC/DOJ Study:

The Federal Trade Commission and the Antitrust Division of the Department of Justice based this report on 27 days of joint hearings from February through October 2003; a

Commission-sponsored workshop in September 2002; and independent research. The hearings broadly examined the state of the health care marketplace and the role of competition, antitrust, and consumer protection in satisfying the preferences of Americans for high-quality, cost-effective health care. A small portion of the study criticized CON as shown in the following Internet links for documents and responses:

- July 2004 Improving Health Care: A Dose of Competition Federal Trade Commission and Department of Justice
- The Federal Trade Commission & Certificate of Need Regulation: An AHPA Critique
- Improving Health Care: A Dose of Competition:

AHPA Response Arguments in Favor of Planning and CON Regulation

- A Dose of Competition: AHPA Response:

Arguments Against FTC Assertions and Assumptions

• Other State Statutes, Rules, and Plans:

Descriptive information was gathered about key states both with and without CON programs to describe purposes, processes, and experiences with efforts to address health care cost, access, and quality (see HCA website above for Internet links):

- Kentucky

Kentucky CON, Statues, and Regulations

- Maine

Procedures Manual and Statutes

- Michigan

CON Site, Statute, Rules, and CON Review Standards, and CON Program Michigan CON Performance Audit, and Follow-Up Report

- Minnesota

Press Release: Governor Pawlenty Unveils 'SMART BUY' Alliance

Minnesota's Smart Buy Alliance: A Coalition of Public/Private Purchasers Demands Quality and Efficiency in Health Care

Minnesota Health Information: A Guide to Health Care Quality and Cost in Minnesota Governor's Health Cabinet

- Missouri

Rulebook, which includes Rules, Statutes, and Process

- New York

Capacity Matters - Finger Lakes Health Systems Agency

Capacity and Use of High Tech Medical Services in Upstate New York

- North Carolina

Statutes, Rules, 2006 State Medical Facilities Plan, and Overview of CON Process Summary of Facilities and Activities Requiring CON

- Ohio

Certificate of Need, Rules, and Chapter 3702: Hospital Care Assurance Program

- Oregon

Certificate of Need and Statutes

Oregon Administrative Rules: Purpose, Applicability, and Definitions for CON

- Vermont

Certificate of Need, Regulations, and Statutes

Appendix A-6 Washington Expert Speakers Providing Professional Input

Joint Legislative Audit and Review Committee

Cynthia L. Forland, Research Analyst Lisa Jeremiah, Research Analyst Ruta Fanning, Legislative Auditor Keenan Konopaski, Audit Coordinator

Department of Health

Gary Bennett, Director,

Facilities and Services Licensing, Health Services Quality Assessment

Bart Eggan, Executive Manager,

Office of Certification and Technical Support, Health Services Quality Assessment

Brian Peyton, Director, Legislative and Constituent Relations

Byron Plan, Executive Manager, Office of Health Care Survey

Janis R. Sigman, Manager, Certificate of Need Program

Jeanette Zaichkin, RNC, MN, Public Health Nurse Consultant, Maternal and Child Health

Department of Social and Health Services

Irene Owens, Office Chief,

Policy, Program Development & Training Unit, Residential Care Services, ADSA **Joyce Pashley Stockwell**, Director, Residential Care Services

Mercer Government Human Services Consulting

Cynthia A. Smith, Principal Kevin Russell, Associate

Health Care Authority

Nancy Fisher, MD, Medical Director Linda M. Glaeser, RN, MS, Director of Quality for Contracted Clinical Programs

Other

Marcia Rohlik, RN, MN, Mason General Hospital Phil Lund, MD, Past President, Washington State Radiology Society Laura Boyd, President, Health Care Purchasers Associations

Washington State Certificate of Need Program Task Force Report

Appendices

Work Group Resources



Appendix B-1

Technical Advisory Committee Worksheet of Health Services and Situations Eligible for Certificate of Need Review (bold underlined reviewed in Washington, bold italics referenced in statute, notes: 1Expansion, 2NO review of service, 3Statutory Guiding Principles)

New	Expsn ¹	NOrv ²	Type of Service	Guiding Principles ³
			Rehabilitation (Level I) Psychiatric (licensed) Obstetrics (Levels II & III)	specific needs of area, accessibility, impact of new health facilities on expenditures specific needs of area, accessibility, impact of new health facilities on expenditures accessibility, effect on facilities for uninsured/underinsured positive impact on outcomes postive impact on outcomes, effect on underinsured/uninsured
			Intensive care unit (ICU)/critical care unit Neonatal ICU (Levels II & III) Adult ICU Pediatric ICU Burn units (specialty)	data to indicate high quality health care, impact on outcomespositive impact on outcomes, underinsured/uninsuredspecific health needs of areasubstantial risk for inappropriate utilization, underinsured/uninsured, total health cost
			Long Term Care Subacute care (Medicare distinct part) Boarding homes (assisted living facility) Specialty care assisted living facility Intermediate care mentally retarded facility Long term care hospital	acessibility, specific health needs of the area specific health needs of area, positive impact on outcomes, state funds to cover cost specific needs of area, positive impact on outcomes, state funds to cover cost
			Medical Equipment Cyber knives Computed tomography (CT) scanners Gamma knives Hyperbaric chambers Magnetic resonance image scanners Positron emission tomography (PET) scanners Positron emission tomography /computed tomography scanners Linear accelerators	total health expenditures, specific health needs of area, impact on quality outcomessubstantial risk for inappropriate utilization, accessibilitytotal health expenditures, specific needs of area, impact on quality outcomessubstantial risk for inappropriate utilizationsubstantial risk for inappropriate utilizationsubstantial risk for inappropriate utilization (cumlative radiation,etc)specific needs of area, state funds to cover increased costspecific needs of area, state funds to cover increased cost

		Behavioral health services Opiate replacement treatment facilities (methadone) Urgent care facilities Diagnostic imaging centers	effect on underinsured/uninsured, accessibility substantial risk for inappropriate utilization, specific needs of area substantial risk for inappropriate utilization, specific needs of area substantial risk for inappropriate utilization, specific needs of area
		Therapeutic cardiac catheterization Elective angioplasty Primary/emergent angioplasty Lithotripsy	positive impact on quality outcomes, substantial risk for inappropriate utilization positive impact on quality outcomes, substantial risk for inappropriate utilization positive impact on quality outcomes, substantial risk for inappropriate utilization substantial risk for inappropriate utilization, postive impact on quality outcomes
		General inpatient surgery suites Outpatient (any freestanding ambulatory) Outpatient (hospital) Open heart (adult) Solid organ transplant (adult) Solid organ transplant (pediatric) Bone marrow/stem cell transplants Single-specialty freestanding ambulatory surgery centers	substantial risk for inappropriate utilization, postive impact on qualtiy outcomes substantial risk for inappropriate utilization, underinsured/uninsured accessibility, positive impact on outcomes, data/QI., total health expenditures accessibility, positive impact on outcomes, data/QI., total health expenditures accessibility, positive impact on outcomes, data/QI., total health expenditures accessibility, total health expenditures, data/quality indicators accessibility, total health expenditures, data/quality indicators substantial risk for inappropriate utilization, underinsured/uninsured, total cost
\boxtimes	\boxtimes		substantial risk for inappropriate utilization, impact on quality and outcomes substantial risk for inappropriate utilization, positive impact on quality outcomes
		Hospice care centers (inpatient) Hospice agencies (outpatient, Medicare/Medicaid) Air ambulance Information technology	specific needs of area, state funds to cover increased cost total health expenditure, state funds to cover increased cost, risk for inappropriate use

Appendix B-1 (continued)

Technical Advisory Committee Worksheet of Health Services and Situations Eligible for Certificate of Need Review

Statutory Guiding Principles

(a version of ESSHB 1688, sections 3(1) and 3(2)(d) abbreviated by the Technical Advisory Committee to more concisely guide their efforts):

The Task Force is to be guided by considering the following principles:

- 1. Impact of the supply of health services on utilization.
- 2. Effect of new health services/facility on expenditures.
- 3. Impact of new health facilities/services/equipment on quality and outcomes.
- 4. Current coverage of facilities and services is to remain.

The Task Force is to develop criteria, including consideration of:

- 1. Public Need:
 - a) Specific health needs of an area
 - b) Positive impact on health indicators of population served
 - c) Substantial risk for inappropriate utilization
 - d) Accessibility for all residents
 - e) Data to indicate quality indicators
- 2. Impact on orderly economic development of health facilities and health resources:
 - a) Impact on total health expenditures
 - b) Affect on existing providers and facilities service for underinsured/uninsured
 - c) Availability of state funds to cover increased cost
 - d) Potential of more effective or accessible or less costly alternatives

Appendix B-2

Task Force Health Facilities, Equipment, and Services Eligible for Certificate of Need Review Summary

(bold underlined currently reviewed in Washington, bold italics - referenced in ESSHB 1688)

Proposed for No Review

Long Term Care

Boarding homes (assisted living facility)
Specialty care assisted living facility
Intermediate care
mentally retarded facility
Swing beds (>5 beds)
Residential care facility

Psychiatric residential treatment facility

Adult family homes

Medical Equipment Hyperbaric chambers

Ultrasound Heart-lung bypass machines

Computed tomography (CT) scanners

Outpatient Services

Behavioral health services
Opiate replacement treatment
facilities (methadone)
Urgent care facilities

Substance abuse services
Community clinic

Community clin **Procedures**

Primary/emergent angioplasty

Lithotripsy

Other Services

Information technology
(needed to support electronic
health records)
Medical office buildings

Medical office building Birthing centers

Proposed for Continued Review

Acute Inpatient

Substance abuse (adult)*
Substance abuse (child/adolescent)*
Intensive care unit (ICU)/
Critical care unit*
Adult ICU*

Medical-surgical licensed beds

Rehabilitation (Level I)
Psychiatric (licensed)

Obstetrics (Levels II & III)

Pediatrics (specialty) includes ICU

Neonatal ICU (Levels II & III)
Burn units (specialty)

Specialty hospitals

(heart, orthopedic, surgical)

Long Term Care

Subacute care (Medicare distinct part)

Long term care hospital

Nursing homes

Swing beds (>5 beds)

Continuing care retirement center

(5-year Medicaid life care requirement)

Procedures

Therapeutic cardiac catheterization

Elective angioplasty

Kidney treatment centers (including hemodialysis)

Surgery

General Inpatient*
Outpatient (hospital)*

Hospital-based ambulatory surgery centers*

Open heart (adult, pediatric)

Solid organ transplant (adult, pediatric)

Bone marrow/stem cell transplants

Freestanding ambulatory surgery centers

open to non-owner practitioners

Other Services

Home health care (Medicare/Medicaid eligible)

Hospice care centers (inpatient)

Hospice agencies (outpatient, Medicare/Medicaid)

Proposed for New Review

Medical Equipment

Cyber knives Gamma knives

Positron emission tomography scanners Positron emission tomography/

computed tomography scanners

Linear accelerators Robotic surgery

Outpatient Services

Freestanding emergency department
Freestanding radiological service centers
Diagnostic imaging centers
Oncology (cancer) treatment centers
Surgery

Cardiac surgery (outpatient and not done under a hospital license)

All ambulatory surgery centers regardless of owner or operator

Proposed for Future Study

Acute Inpatient

Conversion of acute care bed type

Long Term Care

Conversion of long term care bed type

Medical Equipment

Magnetic resonance image scanners

Procedures

Diagnostic cardiac catheterization

Surgery

Physician practice office-based surgery

Other Services

Research and demonstration projects

Air ambulance

Home health care

(regardless of payment source)

Hospice agencies

(regardless of payment source)

*These are part of hospital review

Appendix B-3 New Health Care Items Recommended for CON Review by Task Force

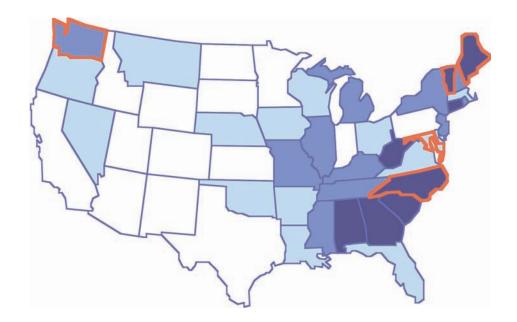
ITEM DESCRIPTION	REVIEW STATES	REF*	RATIONALE
Medical equipment			
Cyber knives	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	2, 4, 5	Avg. cost: \$7,000,000, very new variation on linear accelerator, significant potential for overuse
Gamma knives	CT, VT, AK, GA, WV, ME, NC, MS, SC, DC, NY, RI, MO, HI, MI, AL, IL, VA, MA	1, 4, 5	Avg. cost: \$4,000,000, old technology, major revenue source for providers, limited use
Positron emission tomography scanners	CT, VT, AK, GA, WV, ME, NC, MS, SC, TN, DC, NY, RI, MO, HI, MI, NH, AL, VA, MA, IA, IL, DE	2, 5	Avg. cost: \$2,200,000, fast growing, major revenue source for providers, significant potential for misuse
Positron emission tomography/ computed tomography scanners	CT, VT, AK, GA, WV, ME, NC, MS, SC, TN, DC, NY, RI, MO, HI, MI, NH, AL, VA, MA, IA, IL, DE	2, 5	Avg. cost: \$3,000,000, fast growing, major revenue source for providers, significant potential for misuse
Linear accelerators	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	2, 4, 5	Avg. cost: \$2,500,000, fast growing, major revenue source for providers, significant potential for misuse
Robotic surgery	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, WA, IA, IL, VA, MT, MD, DE, MA, NV	2, 4, 5	Avg. cost: \$1,000,000, very new technology, moderate growth, potential uses still under development
Outpatient services			
Freestanding emergency departments	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, IA, IL, VA, MT, MD, DE, MA, NV	2, 3, 5	Min. cost: \$3,000,000, growing outpatient trend, major revenue source, very high potential for misuse
Diagnostic imaging centers	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, IA, IL, VA, MT, MD, DE, MA, NV	2, 3, 5	Min. cost: \$3,000,000, growing outpatient trend, major revenue source, very high potential for misuse
Freestanding radiological service centers	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	1, 4, 5	Min. cost: \$4,000,000, fast growing, major revenue source, outpatient growth is booming, quality is concern
Oncology (cancer) treatment centers	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, MO, HI, MI, NH, AL, IA, IL, VA, MD, DE, MA	1, 4, 5	Min. cost: \$4,000,000, fast growing, major revenue source, outpatient growth is booming, quality is concern
Surgery			
Ambulatory surgery centers (regardless of owner or operator)	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, WA, IA, IL, VA, MT, MD, DE, MA, NV	2, 3, 5	Min. cost: \$1,000,000, huge outpatient trend, major revenue source, often duplicates inpatient capacity
Cardiac	CT, VT, AK, GA, WV, ME, NC, SC, MS, TN, DC, NY, KY, RI, HI, MI, NH, AL, WA, IA, IL, VA, MT, MD, DE, MA, NV	1, 5	Min. cost: \$1,000,000, huge outpatient trend, major revenue source, often duplicates inpatient capacity

*Task Force Recommended Criteria for CON Review and Regulation of Additional Health Services

Any health care facility, major medical equipment or health service will be subject to review if one or more of the following conditions exist:

- 1. Tertiary services whose clinical quality and/or cost effectiveness is directly and demonstrably tied to volume, including high-risk tertiary services that require complex multi-specialty interactions.
- 2. New, additional or changed services that may have a significant adverse impact on the existing health delivery systems' infrastructure ability to continue to provide essential services to all residents in an economically feasible manner, or cause substantial imbalance of resident access to such services.
- 3. New or existing health care facility, service, or major medical equipment for which there is inequitable state regulatory oversight.
- 4. Emerging or existing devices, technology and services for which clinical efficacy and patient safety have not been fully established.
- 5. Emerging or existing devices, technology and services for costly procedures whose appropriate utilization has not been established, and for which there is a risk of inappropriate utilization.

Appendix B-4 Other Issues Worksheet



Comparison of Selected State Health Plans

The following is a sampling of state health plans prepared for comparison and evaluation. The actual table of contents from each has been captured and displayed to fit on a single page for each example.

The state samples include Maine, Maryland, North Carolina, Vermont, and Washington. A synthesis of samples has also been provided to capture some of the important features of each. The publication dates vary from as old as 1987 to as recent as 2006.

When comparing these samples, there are common components including:

- RATIONALE: vision, purpose, mission, principles;
- PARTICIPANTS: state agencies, providers, purchasers, consumers, advocates;
- EXISTING SYSTEMS: health status, inventory facilities/equipment/services, data;
- PROPOSED DESCRIPTION: health system at a given planning horizon;
- ACTION PLANNING: goals, objectives, criteria, standards, priorities, strategies;
- EVALUATION: monitoring, data reporting, feedback, updating; and
- APPENDICES: planning areas, acronyms, references, others.

This information is intended to provide an array of options from which to choose a potential "model" outline for a state health plan. Certificate of Need is seen as a valuable component and implementation tool within that plan.

State Health Plan: Maine

Part 1: Introduction

Why a State Health Plan? Statutory Requirements The Case for a One-Year State Health Plan

Part 2: One-Year State Health Plan

Section 1: Maine's Major Health Issues

- Objective 1: Develop strategies to reduce the use of emergency departments for Mainers experiencing a psychiatric crisis
- Objective 2: Develop strategies to improve outcomes and reduce costs of treatment of substance abuse and co-occurring disorders
- Objective 3: Convene a Governor's Working Group on the Health System and the Prevention, Early Detection, Effective Treatment, and Rehabilitation of Chronic Illnesses

Section 2: Cost

- Objective 4: Work to ensure the appropriateness and quality of care by identifying variations in practice patterns, utilization of services and outcomes of care
- Objective 5: Continue Maine's historic work to ensure our citizens have access to needed pharmaceuticals at reasonable and affordable prices
- Objective 6: Provide Guidance for Determining the Level of Future Investment in Health Care Services, the Issuance of Certificates of Need and Related Lending Decisions
- Objective 7: Strengthen Maine's Certificate of Need Program by setting out criteria for prioritizing projects that are submitted for review and approval
- Objective 8: Establish Statewide Health Expenditure Targets for Maine
- Objective 9: Promote the Concept of Paying for Performance (PFP) to Public Purchasers Section 3: Quality
 - Objective 10: Improve Maine's Data and Information Technology Systems to Facilitate Improvements In Quality of Care
- Objective 11: Develop framework for comprehensive integrated, patient-level data system Section 4: Access
 - Objective 12: Reduce the number of uninsured Mainers by 31,000
 - Objective 13: Preserve the fiscal and programmatic integrity of DirigoCare as a safety net to cover Maine's lowest income citizens
 - Objective 14: Develop a resource inventory by region documenting health, mental health, substance abuse, public health and long term care resources and workforce

Part 3: Process For First Biennial State Health Plan

The planning process will have five components

Baseline of credible, regionalized data on cost, quality, access and health status

Regional process through 3 regional workgroups to engage all stakeholders to examine data, set regional goals and benchmarks

Statewide campaign "Tough Choices" to determine the public's priorities for health and health care State-level synthesis of regional and State Health Plans

Timeline for Development of Biennial State Health Plan

- Appendix 1. State Health Plan Regions
- Appendix 2. Technical notes for State Health Plan Figures
- Appendix 3. State Health Expenditure Report Category Definitions
- Appendix 4. Members of the Advisory Council on Health Systems Development
- Appendix 5. Governor's Office of Health Policy and Finance

The State Health Plan for Facilities and Services: Maryland TABLE OF CONTENTS*

- .01 Incorporation by Reference
- .02 Introduction
 - A. Purposes of the State Health Plan
 - B. Legal Authority and Overview
 - C. Organizational Setting of the Commission
 - D. Plan Content
 - E. Applicability
- .03 Principles for Planning Specialized Health Services
 - A. Introduction
 - B. Statement of Principles
- .04 Issues and Policies
 - A. Relationship Between Volume and Outcome
 - B. Outcome Data Reporting
 - C. Assessment of Future Changes in Cardiovascular Care
 - D. Variations in Cardiac Surgery Use Rates
 - E. On-Site Cardiac Surgical Backup in Hospitals Performing Percutaneous Coronary Intervention
 - F. Merged Hospital Systems
 - G. Inter-State Cooperation in Health Data Collection
 - H. Inter-Hospital Transport
 - I. Regional Service Areas for Cardiac Surgery Services
- .05 Commission Program Policies
 - A. Utilization Projection Policies
 - B. Consideration of New Program
 - C. Approval Policies
 - D. Waiver from Policies
- .06 Certificate of Need Review Standards
 - A. General Standards
 - B. Cardiac Surgery Standards
- .07 Methodology for Projecting Utilization of Cardiac Surgery
 - A. Period of Time Covered
 - B. Age Groups and Services
 - C. Patient Migration
 - D. Assumptions
 - E. Publication and Recomputation of Utilization Projections
 - F. Procedure to Project Cardiac Surgery Utilization by the Adult Population
 - G. Procedure to Project Cardiac Surgery Utilization by the Pediatric Population
- .08 Definitions

Appendix

A. Requirements for Primary Percutaneous Coronary Intervention Programs

*NOTE: this general format is used as the table of contents for each of the services reviewed including cardiac surgery and percutaneous coronary intervention services (shown here), psychiatric services, emergency medical services, nursing homes, acute inpatient rehabilitation services, acute inpatient services, ambulatory surgery services, acute hospital inpatient obstetric services, alcoholism and drug abuse intermediate care facility treatment services, organ transplant services, and neonatal intensive care services.

State Medical Facilities Plan: North Carolina

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Chapter 4. Statement of Policies:

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Adult Care Homes

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End-Stage Renal Disease Dialysis Services Mental Health, Developmental Disabilities, and

Substance Abuse (General)
Psychiatric Inpatient Services

All Health Services

Acute Care Facilities and Services

Chapter 5. Acute Care Beds

Chapter 6. Operating Rooms

Chapter 7. Other Acute Care Services:

Open Heart Surgery Services Heart-Lung Bypass Machines Burn Intensive Care Services

Transplantation Services

Chapter 8. Inpatient Rehabilitation Services

Technology and Equipment

Chapter 9. Technology:

Lithotripsy

Gamma Knife

Radiation Oncology Services - Linear Accelerators

Positron Emission Tomography Scanner

Magnetic Resonance Imaging

Cardiac Catheterization and Cardiac Angioplasty Equipment

Long-Term Care Facilities and Services

Chapter 10. Nursing Care Facilities

Chapter 11. Adult Care Homes

Chapter 12. Home Health Services

Chapter 13. Hospice Services

Chapter 14. End-Stage Renal Disease Dialysis Facilities

Chapter 15. Psychiatric Inpatient Services

Chapter 16. Substance Abuse, Detoxification, Inpatient and Residential Services

Chapter 17. Intermediate Care Facilities for the Mentally Retarded

Appendices

Appendix A: North Carolina Counties by Health

Appendix B: Partial Listing of Health Planning Acronyms

Appendix C: List of Contiguous Counties

Appendix D: Certificate of Need Law

Appendix E: Regulation of Detoxification Services Provided in Hospitals Licensed under Article 5, Chapter 13 IE, of the General Statutes

Health Resource Allocation Plan: Vermont

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Glossary of Terms

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Hospital-Based Outpatient Services

Hospital-Based Mental Health/Substance Abuse Services

Emergency Medical Services

Major Medical Equipment

Access to Hospital Services

Vermont Hospital Monograph Series Hospital Service Area

Analysis

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Oral Health Services

Ambulatory Mental Health/Substance Abuse Services

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Long-Term Care Services

Community-Based Mental Health/Substance Abuse Services

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Section Four

Certificate of Need (CON) Standards

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- HEALTH SYSTEM PRINCIPLES TO GUIDE STATE HEALTH POLICY/PLANNING THE HEALTH OF STATE RESIDENTS HEALTH GOALS AND OBJECTIVES

VOLUME II: PERFORMANCE STANDARDS FOR HEALTH FACILITIES AND SERVICES A. INTRODUCTION B. HEALTH FACILITY/SERVICE PERFORMANCE STANDARDS

- - Application of Performance Standards
 General Performance Standards for Health Facilities and Services
 - 3. Acute Care Service Performance Standards
 - a. Genera1

 - a. General
 b. Obstetric and Neonatal Services
 c. Pediatric Services
 d. Cancer Management Services
 e. Critical Care Services
 f. Cardiovascular Disease Services
 g. End-Stage Renal Disease Services
 h. Facility Based Adult Rehabilitation Medicine Services
 i. Computed Tomography Services
 i. Magnetic Resonance
 - i. Magnetic Resonance
 k. Innovative Technologies
 l. Ambulatory Surgery
 m. Short Stay Psychiatric Services
 4. Long Term Care Service Performance Standards
 a. Nursing Home Services
 b. Swing Bed Services
 c. Continuing Care Retirement Communities
 d. Home Health Services
 e. Hospice Services
- e. Hospice Services C. FORECASTING METHODS
 - 1. Introduction
 - 2. Operating Room Need Method

 - a. Summary b. Detailed Method
 - 1) Assumptions
 2) General Provisions
 3) Specific Steps and Provisions
 4) Adjustment of Baseline Nursing Home Need
 3. Nursing Home Bed Need Projection Method
 - - a. Summaryb. Detailed Method

 - (1) Assumptions
 (2) General Provisions
 (3) Specific Steps and Provisions
 (4) Adjustment of Baseline Nursing Home Need Projections
 (5) Data Sources and Methods
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 - (6) Definitions
 - 4. Hospital Bed Need Forecasting Method
 - a. Introduction
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 - c. Criteria and Standards for Evaluation and Use of Method
 - (1) Definitions (2) General Principles
 - (3) Criteria and Standards d. Specific Methods

 - (1) Determination of Forecasting Policy
 (2) Methods of Overall Forecasts of Non-Psychiatric Bed Needs
 (3) Methods for Service Specific Forecasts
 (4) Short-Stay Psychiatric Bed Forecasting Method
 e. Guidelines for Adjusting Forecasts
 (1) Caparal Adjustment Guidelines

 - (1) General Adjustment Guidelines (2) Psychiatric Adjustments

APPENDICES

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APPENDIX B: REQUIREMENTS FOR CONTINUING CARE RETIREMENT COMMUNITY PROJECTS

GLOSSARY OF TERMS

ACRONIVAGUISTE MEDIANI ACRONYMS USED IN PLAN

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- Purpose of the State Health Plan
- Implementation of the State Health Plan

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- Geographic and Environmental Characteristics
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- Accessibility
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CHAPTER V: PRIORITIES

- Health System Principles
- Statewide Health Issues
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CHAPTER VI: SERVICE SPECIFIC PLANS

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- Mental Health Services
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 - o (listing)
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 - o (listing)
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 - o (listing)

CHAPTER VII: STATE HEALTH POLICIES AND PROGRAMS

- Overview of State Health Policies and Programs
- A Health Care Cost Containment Strategy
- Evaluation of the State Health Plan

Washington State Certificate of Need Program Task Force Report

Appendices

Recommended Legislative Changes



Appendix C-1 Recommended Legislative Changes to RCW 70.38.015

Recommended Changes to RCW 70.38.015 (subsections 1, 2, 3, 4, 5, 6)	Existing	Revised	New
It is declared to be the public policy of this state:			
(1) That <u>a strategic</u> health planning <u>process</u> , to <u>promote</u> , <u>maintain</u> , and <u>assure the</u> health of all citizens in the state, to provide accessible health services, health manpower, health facilities, and other resources while controlling excessive increases in costs, and to recognize prevention as a high priority in health programs, is essential to the health, safety, and welfare of the people of the state. Health planning should be responsive to changing health and social needs and conditions, is essential to the health, safety, and welfare of the people of the state, and that it be undertaken biennially by a designated state agency or body;		X	
a) To promote, maintain, and assure the health of all citizens in the state:		X* X	
b) To provide accessible health services, health <u>manpower workforce</u> , health facilities, and other resources:		X	
c) <u>To while controlling excessive increases in costs:</u>		X*	
d) To apply specific quality criteria and population health indicators;			X
e) To recognize prevention as a high priority in health programs;		X*	
f) To address periodic priority issues including disaster planning, public health threats, public safety dilemmas, and others;			X
g) To coordinate efforts among state agencies including facility, services and professional provider licensure; state and federal reimbursement; health service utilization data systems; and others;			X
h) To promote a sentinel role that recognizes the close interrelationship of these concerns and emphasizes cost control of health services, including cost-effectiveness and cost-benefit analysis; and			X
i) To integrate criteria for evidence-based medicine and into the process;			X
(2) Involvement in health planning from That both consumers and providers throughout the state should shall be encouraged involved in this health planning process, outcomes of which shall be clearly articulated and available for public review and use;		X	
(2) That the development of health services and resources, including the construction, modernization, and conversion of health facilities, should be accomplished in a planned, orderly fashion, consistent with identified priorities and without unnecessary duplication or fragmentation;		X	
(3) That the certificate of need program is a component of a health planning regulatory process that:			X
a) Contributes to state health plan and public policy goals that are: i) Clearly articulated, and ii) Regularly updated;			X
b) Balances considerations of: i) Access to quality care at a reasonable cost for all residents; ii) The optimal use of existing health care resources; iii) Fostering of expenditure control; and iv) Unnecessary duplication of health care facilities and services;			X

Recommended Changes to RCW 70.38.015 (subsections 1, 2, 3, 4, 5, 6)	Existing	Revised	New
 c) Supports improved health care outcomes by: i) Basing decisions on the best available evidence and information, and ii) Continuously monitoring compliance; 			X
d) Is accountable for maintaining the resources necessary for quality, timely, and consistent decisions;			X
e) Regularly evaluates the impact of capacity management on health services expenditures, access, quality, and innovation;			X
f) Utilizes detailed criteria, standards and need methodologies, both general and service/facility specific, that are updated at least biennially, after consultation with a Technical Advisory Committee;			X
g) Is conducted in a transparent and accountable manner;			X
h) Provides request-for-proposal invitations for CON proposals based on service needs determined in the state health plan; and			X
 i) Use expedited abbreviated cycles for applications that comply with the state health plan and have minimal impact on area health services; 			X
(34) That the development and <u>ongoing</u> maintenance of adequate health care information, statistics, and projections of need for health facilities and services is essential to effective health planning and resources development; at a minimum, the data system shall support the review and monitoring of the specified health care facilities and services regulated by the certificate of need <u>program</u> ;		X	
(4 <u>5</u>) That the development of nonregulatory other approaches to health care expenditure control should shall be considered, including the strengthening of price competition; and		X	
(56) That strategic health planning should shall be concerned with public health and health care financing, access, and quality, recognizing their close interrelationship and emphasizing cost control of health services, including cost effectiveness and cost-benefit analysis the stability of the health system, encompassing health care financing, quality, and the availability of information and services for all residents.		X	

^{*}Technical corrections to improve readability without changing intent or meaning.

Appendix C-2 Recommended Legislative Changes to RCW 70.38.025

Recommended Changes to RCW 70.38.025 (subsections 6, and new)	Existing	Revised	New
(6) "Health care facility" means hospices, hospice care centers, hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers, ambulatory surgical facilities, and home health agencies, freestanding emergency departments, freestanding radiological service centers, diagnostic imaging centers and oncology (cancer) treatment centers, and includes such facilities when owned and operated by a political subdivision or instrumentality of the state and such other facilities as required by federal law and implementing regulations, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy. In addition, the term does not include any nonprofit hospital: (a) Which is operated exclusively to provide health care services for children; (b) Which does not charge fees for such services; and (c) If not contrary to federal law as necessary to the receipt of federal funds by the state.		X	
(16) "Major medical equipment" means acquisition of gamma knives, positron emission tomography scanners (including PET/CT), linear accelerators (including cyber knives), and robotic surgery.			X
(17) "New health service" means cardiac surgery, and ambulatory surgery centers, regardless of owner or operator.			X

Appendix C-3 Recommended Legislative Changes to RCW 70.38.105

Recommended Changes to RCW 70.38.105 (subsection 4 and new)	Existing	Revised	New
(4) The following shall be subject to certificate of need review under this chapter;	X		
(a) The construction, development, or other establishment of a new health care facility;	X		
(b) The sale, purchase, or lease of part or all of any existing hospital as defined in RCW 70.38.025;	X		
(c) Any capital expenditure for the construction, renovation, or alteration of a nursing home which substantially changes the services of the facility after January 1, 1981, provided that the substantial changes in services are specified by the department in rule;	X		
(d) Any capital expenditure for the construction, renovation, or alteration of a nursing home which exceeds the expenditure minimum as defined by RCW 70.38.025. However, a capital expenditure which is not subject to certificate of need review under (a), (b), (c), or (e) of this subsection and which is solely for any one or more of the following is not subject to certificate of need review: (i) Communications and parking facilities; (ii) Mechanical, electrical, ventilation, heating, and air conditioning systems; (iii) Energy conservation systems; (iv) Repairs to, or the correction of, deficiencies in existing physical plant facilities which are necessary to maintain state licensure, however, other additional repairs, remodeling, or replacement projects that are not related to one or more deficiency citations and are not necessary to maintain state licensure are not exempt from certificate of need review except as otherwise permitted by (d)(vi) of this subsection or RCW 70.38.115(13); (v) Acquisition of equipment, including data processing equipment, which is not or will not be used in the direct provision of health services; (vi) Construction or renovation at an existing nursing home which involves physical plant facilities, including administrative, dining areas, kitchen, laundry, therapy areas, and support facilities, by an existing licensee who has operated the beds for at least one year; (vii) Acquisition of land; and (viii) Refinancing of existing debt;	X		
(e) A change in bed capacity of a health care facility which increases the total number of licensed beds or redistributes beds among acute care, nursing home care, and boarding home care if the bed redistribution is to be effective for a period in excess of six months, or a change in bed capacity of a rural health care facility licensed under RCW 70.175.100 that increases the total number of nursing home beds or redistributes beds from acute care or boarding home care to nursing home care if the bed redistribution is to be effective for a period in excess of six months, or a change in the types of services in a health care facility. A health care facility certified as a critical access hospital under 42 U.S.C. 1395i-4 may increase its total number of licensed beds to the total number of beds permitted under 42 U.S.C. 1395i-4 for acute care and may redistribute beds permitted under 42 U.S.C. 1395i-4 among acute care and nursing home care without being subject to certificate of need review. If there is a nursing home licensed under chapter 18.51, RCW within twenty-seven miles of the critical access hospital, the critical access hospital is subject to certificate of need review except for: (i) Critical access hospitals which had designated beds to provide nursing home care, in excess of five swing beds, prior to December 31, 2003; or (ii) Up to five swing beds. Critical access hospital beds not subject to certificate of need review under this subsection (4)(e) will not be counted as either acute care or nursing home care for certificate of need review purposes. If a health care facility ceases to be certified as a critical access hospital under 42 U.S.C. 1395i-4, the hospital may revert back to the type and number of licensed hospital beds as it had when it requested critical access hospital designation;		X	

Recommended Changes to RCW 70.38.105 (subsections 4 and new)	Existing	Revised	New
(f) Any new tertiary health services which are offered in or through a health care facility or rural health care facility licensed under RCW 70.175.100, and which were not offered on a regular basis by, in, or through such health care facility or rural health care facility within the twelve-month period prior to the time such services would be offered;	X		
(g) Any expenditure for the construction, renovation, or alteration of a nursing home or change in nursing home services in excess of the expenditure minimum made in preparation for any undertaking under subsection (4) of this section and any arrangement or commitment made for financing such undertaking. Expenditures of preparation shall include expenditures for architectural designs, plans, working drawings, and specifications. The department may issue certificates of need permitting predevelopment expenditures, only, without authorizing any subsequent undertaking with respect to which such predevelopment expenditures are made; and		X*	
 (h) Any increase in the number of dialysis stations in a kidney disease center- (i) Major medical equipment including gamma knives, positron emission tomography scanners (including PET/CT), linear accelerators (including cyber knives), and robotic surgery, and 		X*	X
(k) New health services including cardiac surgery, and ambulatory surgery centers, regardless of owner or operator.			X
(7) All health care facilities, major medical equipment and new health services that require a certificate of need shall be licensed or certified by state government.			X
(8) No state agency charged by statute to license or certify the facilities and services which require certificate of need review shall issue a license to or certify any such facility or service, or distinct part of such, that is developed without first obtaining a certificate of need.			X
(9) No agency of state government may appropriate or grant funds to or make payment of any funds to any person, health care facility or health care service which has not first obtained every certificate of need required.			X
(10) Application fees and other sources of revenue shall be sufficient to cover the specific or direct costs of CON monitoring and other related costs and systems including data systems.			X

^{*}Technical corrections to improve readability without changing intent or meaning.

Appendix C-4 Recommended Legislative Changes to RCW 70.38.115

Recommended Changes to RCW 70.38.115 (subsections 1, 2, 4, 5)	Existing	Revised	New
(1) Certificates of need shall be issued, denied, suspended, or revoked by the designee of the secretary in accord with the provisions of this chapter and rules of the department that develops review criteria and which establishes review procedures and criteria for the certificate of need program.		X	
•			
(2) Criteria for the review of certificate of need applications, except as provided in subsection (3) of this section for health maintenance organizations, shall include but not be limited to consideration of the following:	X		
(a) The need that the population served or to be served by such services has for such services Community need for the proposed services, based on current utilization data and trends;		X	
(b) The availability of less costly or more effective alternative methods of providing such services;	X		
(c) The financial feasibility and the probable impact of the proposal on the cost of and charges for providing health services in the community to be served, including the impact on the current health system infrastructure and ability of existing providers to serve the under-insured and uninsured;		X	
 (d) In the case of health services to be provided, (i) the availability of alternative uses of project resources for the provision of other health services, (ii) the extent to which such proposed services will be accessible to all residents of the area to be served, and (iii) the need for and the availability in the community of services and facilities for osteopathic physicians and surgeons and allopathic physicians health care providers and their patients. The department shall consider the application in terms of its impact on existing and proposed institutional and other educational training programs for doctors of osteopathic medicine and surgery and medicine for health practitioners at the student, internship, and residency training levels; 		X	
 (e) In the case of a construction project, the costs and methods of the proposed construction, including the cost and methods of energy provision, and the probable impact of the construction project reviewed (i) on the cost of providing health services by the person proposing such construction project and (ii) on the cost and charges to the public of providing health services by other persons; 	X		
(f) The special needs and circumstances of osteopathic hospitals, nonallopathic services and children's hospitals;		X	
(g) The needs of special populations;			X
(gh) Improvements or innovations in the financing and delivery of health services which that foster cost containment and serve to promote quality assurance and cost-effectiveness;		X*	
(hi) In the case of For health services proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed;		X*	
(ij) In the case of For existing services or facilities, the quality of care provided by such services or facilities in the past;		X*	

Recommended Changes to RCW 70.38.115 (subsections 1, 2, 4, 5)	Existing	Revised	New
(jk) In the case of hospitals certificate of need applications, whether the hospital applicant meets or exceeds the regional average level of charity care, as determined by the secretary; and whether the applicant has adopted policies consistent with the charity care and reporting requirement of RCW 70.170.060;		X	
 (kl) In the case of For nursing home applications: (i) The availability of other nursing home beds in the planning area to be served; and (ii) The availability of other services in the community to be served. Data used to determine the availability of other services will include but not be limited to data provided by the department of social and health services. 		X*	
(m) For other CON regulated services, whether the applicant has made provisions for charity care commensurate with current community standards for the service(s) to be offered;			X
(n) The availability of appropriate health care workers to deliver the proposed service; and			X
(o) Whether the applicant agrees to provide services to medicaid and medicare enrollees and agrees to not discriminate against medicaid and medicare enrollees based upon their coverage.			X
(4) Until the final expiration of the state health plan as provided under RCW 70.38.919, <u>t</u> The decision of the department on a certificate of need application shall be consistent with the <u>a</u> state health plan-in effect, that is <u>updated at least biennially</u> , except in emergency circumstances which that pose a threat to the public health. The department in making its final decision may issue a conditional certificate of need if it finds that the project is justified only under specific circumstances. The conditions shall directly relate to the project being reviewed. The conditions may be released if it can be substantiated that the conditions are no longer valid and the release of such conditions would be consistent with the purposes of this chapter.		X	
(5) Criteria adopted for review in accordance with subsection (2) of this section may vary according to the purpose for which the particular review is being conducted or the type of health service reviewed. Criteria, standards, and methods for determining need shall be reviewed and updated at least biennially after consultation with a technical advisory committee.		X	

^{*}Technical corrections to improve readability without changing intent or meaning.

Appendix C-5 Recommended Legislative Changes to RCW 70.38.125

Recommended Changes to RCW 70.38.125 (subsection 3, and new)	Existing	Revised	New
(3) The department shall <u>initially</u> monitor the approved projects to assure conformance with certificates of need that have been issued <u>until completion</u> . Following completion of an approved project, the department shall continue to monitor compliance for five years. Rules and regulations adopted shall specify when changes in the project require reevaluation of the project. The department may require applicants to submit periodic progress reports on approved projects or other information as may be necessary to effectuate its monitoring responsibilities.		X	
(7) The department shall enforce penalties for non-compliance with provisions and conditions of the approved certificate of need application, using provisions to include curtailment of services and fines defined by rules and regulations.			X

Appendix C-6 Recommended Legislative Changes to RCW 70.38.135

Recommended Changes to RCW 70.38.135 (subsection 3 and new)	Existing	Revised	New
 (3) Upon review of recommendations, if any, from the board of health: (a) Promulgate rules under which health care facilities, major medical equipment and health service providers doing business within the state shall submit to the department such data defined in RCW 43.70.052 related to health and health care as the department finds necessary to the performance of its functions under this chapter including at least those facilities, equipment and services which require certificate of need review; (b) Promulgate rules pertaining to the maintenance and operation of medical facilities which receive federal assistance under the provisions of Title XVI; (c) Promulgate rules in implementation of the provisions of this chapter, including the establishment of procedures for public hearings for predecisions and post-decisions on applications for certificate of need; (d) Promulgate rules providing circumstances and procedures of expedited certificate of need review if there has not been a significant change in existing health facilities of the same type or in the need for such health facilities and services, and that comply with the state health plan and have minimal impact on area health services; 		X	
(6) Provide invitations for CON proposals in response to service needs determined in the state health plan; and			X
(7) <u>Utilize evidence-based health care criteria and standards consistent with the state health plan. State health plan criteria shall be updated at least biennially.</u>			X

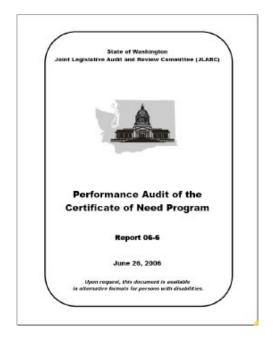
Appendix C-7 Recommended Legislative Changes to RCW 43.70.052

Recommended Changes to RCW 43.70.052 (new subsection)	Existing	Revised	New
Recommended Changes to RCW 43.70.052 (new subsection) (6) The department shall collect data as follows: (a) The data for CON analysis and monitoring shall be a subset of a comprehensive data system for state health planning which includes improved data collection methodology and reporting consistent with technological advances; (b) There shall be ongoing CON data collection acquired and reported by a state agency using consistent and reliable performance measures; (c) Data, as it relates to CON reviewable services, shall include comprehensive inpatient and outpatient data, and financial and utilization information related to charity care, quality, and cost regardless of the service location; (d) Data shall be publicly available for applicants and observers; and (e) Data collected in this process may produce indications for quality improvement, performance improvement and other quality of care issues shall be reported to the state planning body and all appropriate agencies whose authority extends to this issue.	Existing	Revised	New

Appendix D-1 Summary Excerpts from JLARC Report

At the June 28, 2006, CON Task Force meeting, the Joint Legislative Audit and Review Committee (JLARC) staff presented a report. It showed the recent results of the JLARC performance audit of the Department of Health's administration of the Certificate of Need program.

The Legislature, in ESSHB 1688, directed that the JLARC Committee perform this audit. The same legislation created the CON Task Force. The Legislature, in Section 3(3) of 1688, directed the Task Force to consider this report during the development of its recommendations on improving and updating the state's Certificate of Need Program.



The Final JLARC Report contained the following six recommendations.

Recommendations:

- 1. DOH should better use the Certificate of Need program's website to make more information on program activities and application forms available to the public.
- 2. The Department of Health should identify strategies for meeting established statutory timelines for Certificate of Need applications.
- 3. DOH should identify strategies to ensure that all statutory criteria for reviewing Certificate of Need applications are fully applied. The Department may also recommend amendments to statutory criteria, if necessary, to reflect the state's current health care system.
- 4. The Legislature should consider establishing consistent basic reporting requirements for all services and facilities that are subject to Certificate of Need review so that information related to each type of application will be readily available and reliable.
- 5. To ensure ongoing consistency in both the analysis and final decisions for Certificate of Need applications, DOH should perform regular and ongoing reviews of program staffs application reviews and issued decisions.
- 6. DOH should revise its monitoring practices to include completed projects, as appropriate, to ensure applicants' compliance with issued Certificates of Need in accordance with statute.

Appendix E-1 Comments